K042904

FEB 1 8 2005

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 20, 2004

Trade Name, Common Name and Classification Name:

A. Trade Name:
Infinity Kappa XLT

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Monitor, physiological, patient (with arrhythmia detection or alarms	MHX	2	870.1025
System, Network and Communication, Physiological Monitors	MSX	2	870.2300
Computers and Software, Medical	LNX		

Predicate Device Identification:
Infinity Explorer (K040945)
Infinity Delta / DeltaXL / Kappa (K033957)
Infinity SC 8000 (K012016)

Device Description:
The Infinity Kappa XLT is an addition to Draeger's INFINITY patient monitoring system that combines on one platform the patient monitoring features of the Infinity Delta/DeltaXL/Kappa and the Infinity Explorer, Draeger's software-driven critical care workstation.

The Kappa XLT System consists of three basic components:

- The Kappa XLT Vital Signs Engine that acquires all signals
- The Kappa XLT Display, a medical grade display unit
- The Kappa XLT Power Supply.

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Intended Use:
The Infinity Kappa XLT is capable of measuring heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, cardiac output, arterial oxygen saturation, pulse rate, apnea, ST Segment Analysis, and 12-Lead ST Segment Analysis. The device produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. The device will connect to an R50 recorder via the Infinity Network. The device is capable of displaying clinical data received over a hospital information system.

Assessment of non-clinical performance data for equivalence:
The Infinity Kappa XLT was tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate devices.

Assessment of clinical performance data for equivalence:
Clinical performance evaluation indicates that the Infinity Kappa XLT is substantially equivalent to the Infinity Delta series monitors and the Infinity Explorer.

Biocompatability:
Not applicable

Sterilization:
Not applicable

Standards and Guidance: IEC 60601-1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Draeger Medical Systems
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K042904
Trade Name: Infinity Kappa XLT
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: Class II (two)
Product Code: 74 MHX
Dated: January 20, 2005
Received: January 21, 2005

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

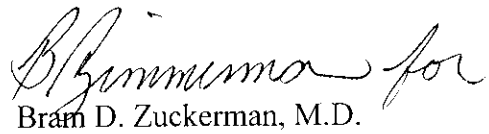
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042904

Device Name: Infinity Kappa XLT

The Infinity Kappa XLT is capable of measuring heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, cardiac output, arterial oxygen saturation, pulse rate, apnea, ST Segment Analysis, and 12-Lead ST Segment Analysis.

The device produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. The device will connect to an R50 recorder via the Infinity Network and is capable of displaying clinical data received over a hospital information system.

Kappa XLT receives EEG signals when connected to an Infinity EEG pod.

The Infinity Trident NMT pod measures the muscle response to electrical stimulation of a peripheral nerve and when connected to a Kappa XLT transmits that information to the device.

The SCIO module sample breathing gases from adults and pediatrics. The gas module continuously measures the content of CO2, N2O, O2 and one of the anesthetic agents, halothane, isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture and communicates real time and derived gas information to Kappa XLT.

With etCO2 the Kappa XLT can measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode; and with etCO2+Respiratory Mechanics, spirometry and carbon dioxide can be monitored.
The device can interface with specific third party devices via an RS 232 connection.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output, ST Segment Analysis, and arrhythmia which are intended for use in the adult and pediatric populations.*

MRI Compatibility Statement:
The Infinity Kappa XLT is not compatible for use in a MRI magnetic field.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042904